



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

George Luntz
Native Remedies, LLC
2061 NW 2nd Ave.
Suite 106
Boca Raton, FL 33431

Dear Mr. Luntz:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.nativeremedies.com> and has determined that the products Triple Complex Diabetonic, Insulate Plus, and Vizu-All Plus are promoted for conditions that cause these products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Insulate Plus

- “Use Insulate Plus regularly to: [b]alance blood sugar levels in order to reduce or remove the need for insulin or hypoglycemic medications....[i]mprove circulation to the feet and hands which prevents diabetic problems with feet and improves the healing of wounds...[i]mprove blood flow to the optical fibres to prevent diabetes-related eye disease...[h]elp reduce the reduce the risk of heart disease”
- “Insulate Plus is a complex herbal remedy that assists in the treatment and prevention of diabetes.”
- (Testimonials) “Because of diabetes I had major problems with my feet and always felt tingling.... Since using Insulate Plus this is a thing of the past....”
- “Insulate Plus contains the following ingredients:... Ggymnema sylvestre:...used in Ayurvedic medicine to treat diabetes for many centuries and can improve blood sugar

control, thereby reducing the need for insulin and hypoglycemic medication....Ginkgo biloba:...help to prevent the tissue damage and poor circulation associated with diabetes....help to treat diabetes-related eye disease.”

Triple Complex Diabetonic

- “Use Diabetonic regularly to:... Relieve symptoms of disease...Safely treat a wide range of symptoms without side effects...”
- “Triple Complex Diabetonic...is an excellent supplement for anyone with diabetes.”
- “Taken regularly, Triple Complex Diabetonic will help to keep sugar levels stable....”
- (Testimonials) “When my doctor told me that I had symptoms of diabetes I was determined to stay away from medication....Taking Insulate Plus and Triple Complex Diabetonic together as you advised me has completely solved the problem.”

Vizu-All Plus

- “Vizu-All Plus has been specially formulated to:... Prevent macular degeneration and cataracts...Prevent and treat glaucoma”
- “The following medicinal herbs were carefully selected for inclusion in Vizu-All Plus:... [B]ilberry...has been shown to be effective in the prevention and treatment of degenerative disease of the retina. It also reduces the incidence of hemorrhage in the eye, often associated with diabetes.”
- (Testimonials) “I want to let you know that I have had problems for ages with my eyes and circulation because of diabetes. My homeopath recommended Vizu-all and after 10 weeks there is an enormous difference!”
- “Therapeutic Dose: Approximately 15 drops in a little water....Preventative dose:...10 drops in a little water....”

Furthermore, these claims are supplemented by the metatags you use to bring consumers to your website. These metatags include “Natural Remedies for Diabetes and Diabetic Control Solutions-New Treatment for Diabetes,” “Herbal Diabetic Solutions-Natural Remedies for Diabetes,” and “Macular Degeneration Treatment-Natural Treatments for Glaucoma.”

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, they are also “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

These products are also misbranded within the meaning of Section 502(f)(1) of the Act, in that the labeling for these drugs fail to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. While reviewing your web site, we noticed that you promoted other products for disease treatment and/or prevention. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your website, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be sent to Quyen Tien, Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Enforcement (HFS-607), 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition